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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,980	02/13/2001	Douglas A. Holtzman	MPI2000-544OMNI	2000

7590 10/22/2003

Intellectual Property Group
MILLENNIUM PHARMACEUTICALS, INC.
75 Sidney Street
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EXAMINER	
PAK, MICHAEL D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/782,980	HOLTZMAN ET AL.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication app ars on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,12,18,53 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 9b in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the search of Group 9a and Group 9b are species of a common genus and that it would not be an undue burden for the Examiner to examine all of these groups together. This is not found persuasive because each group is directed to potassium channel with different structures. The different structure requires a separate search in all the databases for each sequences. Furthermore, the difference in function due to difference in structure must be searched as well.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-7, 12, 18, 53 and 54 drawn to STMST2 are examined below. The claims 8-11, 13-17, 19-52 and 55-71 have been withdrawn as being drawn to non-elected invention.

Claim Objections

3. Claim 1 is objected to because of the following informalities. The term numbering "d" is duplicated and is missing an "e". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-7, 12, 18, 53 and 54 are rejected under 35 U.S.C. 101 because the

claimed invention is not supported by either a substantial asserted utility or a well established utility.

The claims are directed to an isolated nucleic acid encoding STMST2 polypeptide which is an orphan G-protein receptor. The specification on page 8 disclose the asserted utility of using the orphan receptor for drug discovery. However, there is no nexus between the claimed protein and the therapeutics for humans. The specification as filed does not disclose or provide evidence that points to a property of the claimed protein such that another non-asserted utility would be well established.. The polypeptide lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Thus, the asserted utility lacks substantial and specific utility because further research to identify or reasonably confirm a "real world" context of use is required. *Brenner V. Manson 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966)* stated that "Congress intended that no patents be granted on an chemical compound whose sole "utility" consists of its potential role as an object of use-testing ... a patent is not a hunting license." *Brenner* further states that "It is not a reward for the search, but compensation for its successful conclusion." Any utility of the nucleic acid encoding the protein or other specific asserted utility is directly dependent on the function of the protein. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion of utility. The claimed polypeptides do not have well established utility because different receptors would have different functions and the skilled artisan would have to determine the function of the orphan receptor. The claimed polypeptides do not substantial utility

because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its function and use. Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. The disclosed use for the nucleic acid molecule of the claimed invention is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence claimed. The claims directed to vectors, host cells, and the process of expressing the protein do not have utility because the nucleic acid without utility is needed to practice the inventions.

Claims 1-7, 12, 18, 53 and 54 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC □112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-7, 12, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and 12 are indefinite because the recitation of two "or" create confusion regarding the whether all the claimed nucleic acids are 90% identical to nucleic acid named or the ATCC deposits are separate.

Claims 1, 12, and 18 recite the term "hybridize" which is a relative term and metes and bounds of the term is not clear. It is suggested that specific hybridization conditions which is supported by the specification be reicited in the claim. Claims 3-7 are dependent on claim 1.

Claims 1 and 12 recite the term "naturally occurring allelic variant" which is ambiguous because the metes and bounds are not clear as to when a nucleic acid is a naturally occurring variant or not. Claims 3-7 are dependent on claim 1.

6. Claims 1-7, 12, 18, 53 and 54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-7, 12, 18, 53 and 54 encompass an isolated nucleic acid encoding variants and fragments of proteins without functional limitations. However, the essential feature of the invention is the nucleic acid molecule which encodes a STMST2 of SEQ ID NO:54, and one of skilled in the art cannot envision the full genus of molecules of the claimed variant nucleic acid molecules. The claims encompass nucleic acid molecule encoding variants whose structure is not known or nucleic acid

molecules encoding other variant proteins with different function from SEQ ID NO:54 taught in the specification. Claimed nucleic acid encoding protein variants encompass a large genus of proteins or channels which are alleles or variants whose function has yet to be identified from different species of animal because the structure of the newly identified naturally occurring protein is not known. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification.

Priority

7. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112.

Claim Rejections - 35 USC 102

8. Claims 1-7, 12, 18, 53 and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Roopa et al. (U.S.20030120057A1).

Roopa et al. disclose nucleic acid encoding protein which has large region 100% identical and similar to SEQ ID NO:54 (see attachment). Roopa et al. disclose vectors, host cells, and array kits comprising the nucleic acid.

The term "complementary" has been interpreted by the examiner to encompass fragments.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
16 October 2003